UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No.1456 Master File No. 01-CV-12257-PBS Subcategory No. 06-CV-11337-PBS
THIS DOCUMENT RELATES TO: *U.S. of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Boehringer Ingelheim Corporation, et al.*, Civil Action No. 07-10248-PBS	Judge Patti B. Saris Magistrate Judge Marianne B. Bowler

THE ROXANE DEFENDANTS' CONSOLIDATED MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO THE GOVERNMENT'S MOTION FOR PARTIAL SUMMARY JUDGMENT

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INTRODUCTION

"Air." "Not a meaningful figure." "Most meaningless for generic drugs." "Not a well-defined concept nor . . . regulated in any way."[1] These are the terms used throughout the relevant period by the federal and state officials charged with administering the Medicare and Medicaid programs to describe the AWPs published in drug pricing compendia. *Describe* AWP is all that even these principal actors can do because the Government has never *defined* AWP by statute or regulation, much less provided any guidance about how manufacturers should report AWP.

Rather than pointing to any actual definition of AWP, the Department of Justice ("DOJ") simply argues its belief that AWP must stand for an empirical average of wholesale prices – a view it first outlined for this Court during the MDL litigation in a thinly-veiled piece of advocacy cloaked as an *amicus curae* brief. It is, however, apparent that no federal or state official has ever shared the DOJ's theories. In fact, even as the DOJ sought to reinvent AWP through its court pleadings, CMS, the federal agency charged with overseeing the Medicare and Medicaid programs, publicized that it "fully encouraged" generic drug acquisition costs of 73% below AWP (*i.e.*, a "spread" of 270%), because they "provide[d] good value to both the beneficiary and the taxpayer."[2] (Rox. 56.1 ¶ 79) The DOJ does not address this or the voluminous evidentiary record created in this case, which demonstrate that the Government was in no way "defrauded" by the nature of published AWPs, particularly with respect to generic drugs.

Instead, the DOJ conjures new standards of liability – standards fundamentally at odds with the legal requirements of the False Claims Act ("FCA"), a "quasi-criminal," punitive statute that

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1 (Rox. 56.1 ¶¶ 11, 18, 46; Rox. 56.1 Reply ¶ 275)

2 For example, if a brand drug costs a provider $100 and is eventually reimbursed by the Government at $130 (a 30% margin), a $10 generic equivalent of that drug would need to result in a reimbursement payment of $40 to net the same $30 margin. In other words, there would need to be a 400% mark-up over the generic's acquisition cost to ensure the provider would receive the same margin for dispensing the generic drug that it receives on the brand drug. Yet, overall, the Government is better served by encouraging the 400% "spread" because it saves $90.

provides for automatic trebling. *See Vermont Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 784-86 (2000). For instance, instead of showing, as it must, that Roxane's AWPs were objectively false based on a controlling statutory or regulatory definition, the DOJ instead attempts to use this Court's 2006 "plain meaning" decision to retroactively fabricate falsity of the AWPs published over the preceding ten-year period. The law, however, prevents this kind of after-the-fact falsity. And, with respect to scienter, the DOJ argues that although Roxane sent its fully discounted average manufacturer prices ("AMPs") for all the Subject Drugs ***directly*** to CMS every quarter, Roxane nonetheless "hid" from this ***same agency*** the fact that published AWPs were not empirical averages, like AMPs. The DOJ provides no logical rationale for how Roxane could seek to defraud CMS with AWPs while simultaneously providing CMS with true average prices – there is none. Moreover, the DOJ entirely ignores multiple rulings by this Court regarding "a perfect storm of information" that by 2001 had revealed the size of large spreads to participants in these programs. *In re AWP Litig.*, 491 F. Supp. 2d 20, 41 (D. Mass. 2007). Simply put, the DOJ provides no basis to prevail as a matter of law on any element of the FCA.

Roxane also moved for summary judgment for a subset of Medicare claims that were based on misclassifications and patent errors by Medicare carriers, including an error arising out of the misclassification of Novaplus-label ipratropium bromide as a brand drug, which the DOJ seeks to capitalize on to inflate theoretical damages by ***$1 billion***. Rather than respond with record evidence, the DOJ instead submits new "facts" in affidavits to fit yet another of its litigation-driven theories, here, that the DMERCs "consistently" followed HCFA regulations while still reaching inconsistent conclusions. But the undisputed record actually created in discovery demonstrates otherwise. The end-result of the DOJ's litigation strategy is that it lacks law and evidence to support its claims, and summary judgment is warranted for Roxane.

I. THE DOJ IS NOT ENTITLED TO PARTIAL SUMMARY JUDGMENT ON THE ELEMENT OF FALSITY.

The requirement that the DOJ show the claims at issue were *objectively* false is not novel: it is the "the *sine qua non* of a [FCA] violation." *U.S. ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002). Yet despite the fact that objective falsity demands proof of a claim "furnished in violation of some controlling rule, regulation, or standard," *U.S. v. Prabhu*, 442 F. Supp. 2d 1008, 1026 (D. Nev. 2006), the DOJ points to *no* actual rule supporting its theory that Roxane was obligated to report AWP as an empirical average price – because there is none. (US Rox. Br. 11-13) Thus, Roxane's conduct cannot be deemed objectively false as a matter of law, especially given this Court's recognition of the "inconsistent and ambiguous information" concerning what price AWP actually measured. *In re AWP Litig.*, 460 F. Supp. 2d 277, 285 (D. Mass. 2006). Moreover, there is overwhelming evidence concerning whether the Government acquiesced in Roxane's usage of AWP. Each of these reasons precludes summary judgment on falsity.

A. The Lack Of An Actual Standard Regarding AWP Precludes A Finding Of Falsity As A Matter Of Law.

Liability under the FCA cannot attach where a defendant has not objectively violated a "law, regulation, or other source" dictating that the claim is false. *U.S. ex rel. Cox v. Iowa Health Sys.*, 29 F. Supp. 2d 1022, 1026 (S.D. Iowa 1998); *see also U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 377 (4th Cir. 2008); *U.S. v. Southland Mgmt. Corp.*, 326 F.3d 669, 674-75 (5th Cir. 2003) (*en banc*).[3] Indeed, the DOJ's own legal authority holds that the statement must be a "palpable lie" as measured against an actual standard. *See U.S. ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1171-72 (9th Cir. 2006) (US Comm. Br. 4). Moreover, any ambiguity regarding statutory or regulatory standards is fatal to the DOJ's case because ambiguity must be construed

[3] (Defs.' Comm. Br. 24-25 (citing additional authorities)); *see also Prabhu*, 442 F. Supp. 2d at 1032-33 (granting summary judgment where there was "no articulated, objective standard that dictates that the documentation underlying the claims is false, inaccurate, or incomplete"); *U.S. ex rel. Roby v. Boeing Co.*, 100 F. Supp. 2d 619, 625 (S.D. Ohio 2000) ("At a minimum, the FCA requires proof of an objective falsehood.") (citations omitted).

against the Government in light of the FCA's punitive treble damage provisions. *See, e.g., U.S. ex rel. Ramadoss v. Caremark, Inc.*, 586 F. Supp. 2d 668, 690-91 (W.D. Tex. 2008). And the factual record here is *replete* with undisputed evidence showing, at minimum, ambiguity as to what reported AWPs were intended to be. (Defs.' Comm. Br. 2-20) Thus, the DOJ's inability to point to *any* predicate statute, regulation, or contract that Roxane objectively violated – much less any shared understanding of reported AWPs – precludes falsity. *See, e.g., U.S. ex rel. Swafford v. Borgess Med. Ctr.*, 98 F. Supp. 2d 822, 828 (W.D. Mich. 2000).

The DOJ's oversight is unsurprising because the undisputed evidence shows that the Government never defined AWP and was well aware that there were ***no*** affirmative obligations on manufacturers to report AWPs in any particular fashion. For example, the Secretary of HHS explicitly told Congress in 1999 that "***AWP is not a well-defined concept nor is it regulated in any way*** . . . and bore no consistent or predictable relationship to the prices actually paid by physicians and suppliers to drug wholesalers in the marketplace." (Rox. 56.1 ¶ 46) Neither Congress nor HCFA/CMS has ever defined AWP. Even today, CMS *continues* to approve of the use of the still-undefined AWP in the majority of State Medicaid programs.

This lack of congressional or regulatory guidance or definition regarding AWP stands in stark contrast to the precise definitions that Congress and HCFA/CMS have imposed when they intend for manufacturers to report specific, empirical prices. For instance, in 1991 (the same year that Medicare began using AWPs), Congress enacted OBRA '90, which required manufacturers to report quarterly AMPs for *every* NDC paid for by the Medicaid program. AMP was not left undefined: there is an elaborate statutory definition for how manufacturers must calculate and report AMPs. *See* 42 U.S.C. § 1396r–8(k)(1)(A).[4] Similarly, when Congress switched Medicare from AWP to an

[4] The Government also knew that AMPs were fundamentally different from AWPs. The OIG had unfettered access to AMPs throughout the relevant time period and explicitly told HCFA/CMS in 1998 that it should base Medicaid rebates on AWPs, rather than AMPs, because AMPs, as actual selling prices, were significantly (Continued…)

empirically-based "average sales price" ("ASP") methodology in 2003, it provided a specific statutory definition of ASP. *See* 42 U.S.C. § 1395w-3a(c). The very existence of AMPs and ASPs negates the DOJ's *post hoc* argument that the Government believed that AWPs were empirical averages of sales prices.[5] If that were true, there would be *no* reason to create and define new terms like AMP and ASP – the Government could have simply used compendia AWPs. It did not do so because it was abundantly clear to the Government that compendia AWPs were not intended to be empirical averages. (Defs.' Comm. Br. 11-20)

It is in this factual context, and under the auspices of a quasi-criminal statute, that the DOJ asks the Court to impose over a ***billion dollars*** worth of liability on Roxane for its use of AWP. It cannot be shown that Roxane violated any objective law, regulation, or other source defining AWP during the relevant period as the DOJ now defines it. This precludes summary judgment. (Defs.' Comm. Br. 24-30) *See, e.g.*, *Borgess Med. Ctr.*, 98 F. Supp. 2d at 828; *Cox*, 29 F. Supp. 2d at 1026 ("A standard billing practice within an industry could hardly be said to be false . . . .")

B. The DOJ Cannot Circumvent Its Duty To Prove Falsity *At The Time Claims Were Submitted* By Merely Invoking This Court's "Plain Meaning" Decision.

The DOJ rests its falsity argument on this Court's 2006 MDL "plain meaning" decision: it does not cite a single regulation or a statute, or any testimony from the numerous depositions of the key officials who ran these programs, as support for its theory that AWP was believed to be an empirical average price during the relevant period. (US Rox. Br. 11) The facts decidedly refute that was ever the case. (Defs.' Comm. Br. 2-20) Placing aside these factual infirmities, the Government's theory is legally unfounded too.

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lower. (Rox. 56.1 ¶ 45 (citing Tab 102, at 2-3, 5); *id.* ¶ 128; *see also* Defs.' Comm. 56.1 ¶¶ 4-5 (noting that CMS Medicaid officials had access to AMPs))

5 The Government cites the 2003 OIG guidelines to argue that AWPs were believed to reflect empirical average prices. But these guidelines explicitly disclaimed any "new law or legal obligations." (Defs.' Comm. 56.1 Resp. ¶¶ 95-96) In fact, the OIG could not have imposed any new law regarding AWP without overstepping its legal authority or supplanting the express policy objectives of Congress and HCFA/CMS. (Defs.' Comm. Br. 29, n.27)

First, in the MDL, this Court sat as a factfinder – a fundamentally different posture from its role at summary judgment. The MDL trial also had a truncated evidentiary record because the DOJ invoked *Touhy* regulations and refused to allow testimony from Government officials. As such, the Court acknowledged that it relied "heavily" on the DOJ's *amicus* brief.[6] *See In re AWP Litig.*, 460 F. Supp. 2d at 279 n.3 (citing Docket No. 3104). The evidence in this case, however, demonstrates that there are triable issues with respect to whether AWPs were "false" under the FCA. *See, e.g., U.S. ex rel. Kersulis v. RehabCare Group, Inc.*, 2007 WL 294122, at *12 (E.D. Ark. Jan. 29, 2007).

Second, the DOJ's Medicaid arguments are not controlled by this Court's Medicare decisions. The DOJ's brief does not address a single federal Medicaid statute or regulation that mentions, let alone defines, AWP.[7] Moreover, the DOJ completely ignores the States' understanding of AWPs – a fatal omission because any "false" Medicaid claims were initially approved by State Medicaid agencies. The Government avoids the evidentiary record that shows that States fully understood the undiscounted nature of AWPs yet continued to use them for policy reasons, especially for generic drugs.[8] (Defs.' Comm. Br. 7-12) *Third*, even on the limited MDL evidentiary record, this Court determined there was ambiguity about what AWP measured. *In re AWP Litig.*, 460 F. Supp. 2d at 285. This also precludes summary judgment on falsity. *See Caremark*, 586 F. Supp. 2d at 690.

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6 The DOJ's *amicus* brief is squarely at odds with the testimony in this case. It can be described, charitably, as having created a "misimpression" and "something on the record that's just wrong." (Ex. A, July 8, 2009 Hr'g Tr. 93-94 (discussing the DOJ's other amicus brief submitted in the New York Counties FUL case)).

7 Nor could it, as there is no federal Medicaid regulation or statute that addresses AWP. 42 C.F.R. § 447.331-32 (federal Medicaid payment regulations) (presently codified at §§ 447.512, 447.514) .

8 The DOJ's global definition of AWP makes no sense because the individual states decide whether to use AWPs in their payment formulae, not the federal government. (*See* Rox. 56.1 Reply ¶ 275; US Comm. 56.1 ¶ 21; Comm. Br. 6-11) Thus, how each Medicaid program understood published AWPs is a critical FCA inquiry. The evidence shows that Medicaid programs did not believe AWP to be an empirical average of selling prices, especially for generic drugs. Nor would Medicaid programs have *discounted* off published AWPs if they understood that benchmark to be fully discounted already, given that State payment rates must ensure provider participation. *See* 42 C.F.R. § 447.204. Under the DOJ's definition of AWP, providers in the following states would be paid on average the following percentages *below* actual cost every time they dispensed a generic drug: Arkansas Medicaid, 20% below cost; Colorado Medicaid, 35% below cost, Connecticut Medicaid, 40% below cost, and Washington Medicaid, 50% below cost. (Rox. 56.1 ¶ 278, Tab 205 (Medicaid formulae))

C. Evidence Of Government Policy Choices Showing Approval Or Acquiescence To Payments Based On Published AWPs Precludes Falsity.

The record shows widespread evidence that the Government purposely relied on AWPs to satisfy legitimate policy objectives, such as incentives to use cheaper generics, cross-subsidization for inadequate dispensing fees, and beneficiary access. (Defs.' Comm. Br. 9-11) As this Court recognized, "[g]overnment knowledge could conceivably be relevant to two elements of the FCA: the falsity of the claim and the defendant's state of mind." *Mass. v. Mylan Labs.*, 608 F. Supp. 2d 127, 148 (D. Mass. 2008).[9] Government approval or acquiescence can preclude FCA liability. *See, e.g.*, *Southland Mgmt. Corp.*, 326 F.3d at 682 n.8 (Jones, J., concurring). Indeed, this Court's holding that "a government knowledge defense [was] viable" in the Massachusetts case rested largely upon a single OIG report. *Mylan Labs.*, 608 F. Supp. 2d at 152. There is significantly more evidence here. (Rox. 56.1 ¶¶ 1-95) Because the evidence shows that the Government chose to continue using AWPs *after* learning of the purported highly "inflated" nature of AWPs, government knowledge can negate falsity and scienter.[10] *See Mylan Labs.*, 608 F. Supp. 2d at 150, 152.

II. THE DOJ CANNOT PROVE SCIENTER ON THIS RECORD.

Scienter is the quintessential fact question and is rarely amenable to summary judgment. *Id.* at 154-55. The DOJ must show that the undisputed evidence conclusively proves that Roxane actually knew about, deliberately ignored, or recklessly disregarded some governing statutory, regulatory, or

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9 This evidence is also relevant to the issue of whether Roxane's conduct was "unjust," a requisite showing for the DOJ's unjust enrichment claims. *See* Restatement (First) of Restitution, § 1 cmt. c.

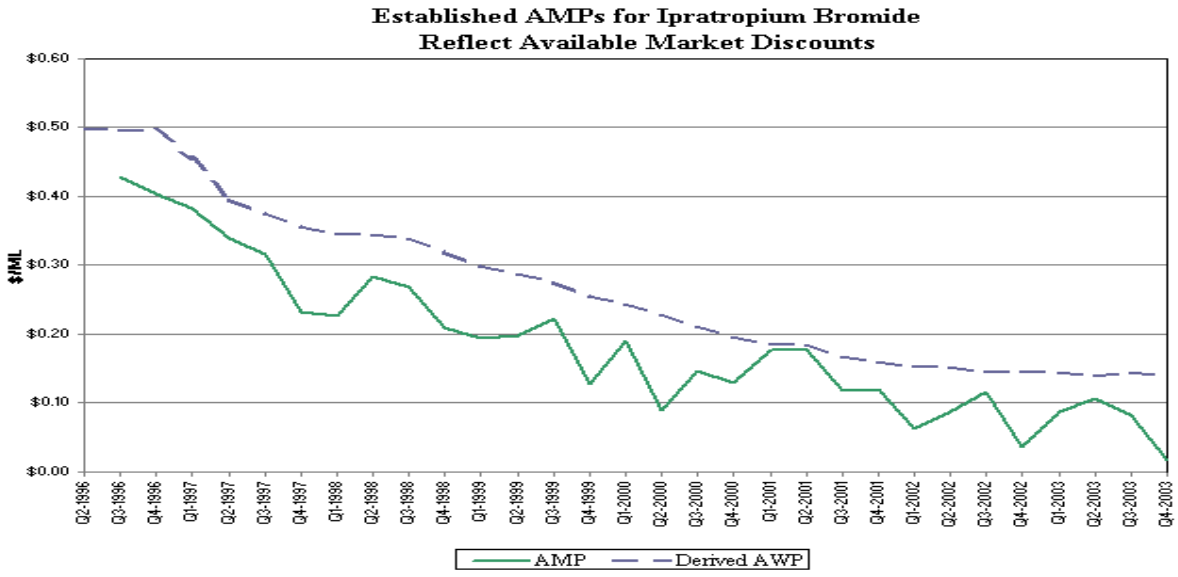
10 Much of the DOJ's argument against approval or acquiescence depends on the fiction that manufacturers' AWPs "controlled" payments (which the programs presumably would not approve of). As an initial matter, Medicaid programs routinely pay for generic drugs based on MAC or FUL prices, which are independent from AWPs. Moreover, neither the Medicare nor any Medicaid program is even required to use compendia AWPs. To the extent Medicaid programs do, they determine discounts from AWPs on a discretionary basis, based on negotiations with providers and other interested parties. The end result is a negotiated rate that balances multiple policy objectives. (Comm. Br. 2-20). Medicare similarly depended on negotiations with providers, and developed a median payment system that results in Medicare paying the same amount for all manufacturers' generic drugs. (*See* Rox. 56.1 ¶¶ 50-73,159, 278) This removes any economic incentive to "manipulate" AWPs. Thus, the payment objectives of these programs bear no resemblance to the DOJ's myopic focus on reducing payments down to actual ingredient cost.

contractual authority clearly requiring published AWPs to reflect actual acquisition costs. *See, e.g., U.S. ex rel. K&R Ltd. P'ship v. Mass. Housing Fin. Agency*, 530 F.3d 980, 983 (D.C. Cir. 2008); *Rehabcare Group, Inc.*, 2007 WL 294122 at *12. This it cannot do because no such authority ever existed and, correspondingly, Roxane cannot have knowingly or recklessly disregarded a nonexistent rule. *See U.S. v. Medica-Rents Co.*, 285 F. Supp. 2d 742, 770-71 (N.D. Tex. 2003); *see also Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 69-70 (2007) ("This is not a case in which the business subject to the Act had the benefit of guidance from the courts of appeals . . . that might have warned it away from the view it took."); *K&R Ltd.*, 530 F.3d at 983-84; c*f. Cox*, 29 F. Supp. 2d at 1026; (Defs.' Comm. Br. 30-32) Moreover, as a punitive statute, the FCA is not the appropriate vehicle to address regulatory noncompliance, mere negligence, or even gross negligence. *K&R Ltd.*, 530 F.3d at 983-84; *U.S. ex rel. Farmer v. City of Houston*, 523 F.3d 333, 338 (5th Cir. 2008); *U.S. ex rel. Quirk v. Madonna Towers, Inc.*, 278 F.3d 765, 768 (8th Cir. 2002); *Caremark*, 586 F. Supp. 2d at 690-91.

Even assuming *arguendo* that some unstated authority required Roxane's AWPs to be empirical averages, the DOJ provides only the conclusory argument that Roxane: (1) knew that its AWPs "bore little to no relation to its actual transaction prices" and (2) was "aware that Medicare and most state Medicaid programs utilized AWPs in setting reimbursement." This falls woefully short. To prove scienter, the DOJ must establish that Roxane ***knew*** (or was reckless in not knowing) that published AWPs were *required* to be based on actual acquisition costs. *See, e.g., City of Houston*, 523 F.3d at 338. The DOJ skips this crucial step because it has no evidence that Roxane's understanding of an industry-wide standard for AWPs was beyond "gross negligence." *See, e.g., K&R Ltd.*, 530 F.3d at 983-84; *Madonna Towers, Inc.*, 278 F.3d at 768 (affirming summary judgment for FCA defendant on lack of scienter where defendant's employees billed Medicare pursuant to what they believed was an "acceptable standard procedure"); *U.S. ex rel. Rose v. E. Tex. Med. Ctr. Reg. Healthcare Sys.*, 2008 WL 4056601 at *5 (E.D. Tex. Aug. 25, 2008). To the contrary, Roxane's corporate designee

testified that Roxane never intended its AWPs to represent or be used as actual averages of customer prices because that was not the industry meaning of AWP.[11] (Rox. 56.1 ¶¶ 99-101)

The DOJ also ignores Roxane's testimony that, because it provided its AMPs directly to HCFA/CMS on a quarterly basis, it had no reason to believe that HCFA/CMS, in direct contravention to standard industry understandings, purportedly considered AWP an undiscounted price. (*Id.* ¶ 102) Unlike AWPs, AMPs were statutorily defined to reflect discounted average prices. Roxane, therefore, had no reason to believe its AWPs should be considered the same. Indeed, as shown in the chart below, the AMPs Roxane sent to HCFA/CMS every quarter are very close to the purported average prices calculated by the DOJ's expert for one of the Subject Drugs:



This renders the DOJ's argument that these prices were "hidden" from HCFA/CMS utterly illogical and counter-factual. The DOJ offers ***no*** explanation of how Roxane could possibly seek to defraud HCFA/CMS through its AWPs while simultaneously reporting to the *same* agency fully-discounted

[11] Other Roxane employees testified similarly. For instance, one employee confirmed that Roxane's convention of establishing AWPs for generic drugs at approximately ten-percent below the brand AWP was "the way generic companies typically set AWPs." (Rox. 56.1 Reply ¶ 99 (citing 7/26/07 Paoletti Dep. 26-27; 11/9/04 Paoletti Dep. 146-47); *see also* (*Id.* ¶ 99 (citing 6/25/02 Feldman Dep. 71 ("Q. If a generic product in general is not 10 percent or more less than the brand AWP, it won't be considered a generic by First Data Bank. Is that true? A. That's true."))); (*Id.* ¶ 99 (citing 11/30/07 Morgan Dep. 21 ("[T]here was a perception in the industry" that generic companies needed to set AWPs ten percent below the corresponding brand to be classified as a generic product)))

AMP prices every quarter that unambiguously showed that published AWPs could not be empirical averages.

Faced with the undeniable fact that Roxane's quarterly AMP submissions to HCFA/CMS negate any semblance of falsity or scienter, the DOJ concocts a litigation-driven (and unsupported) theory that HCFA/CMS was limited in considering AMPs in relation to AWPs – purportedly because of manufacturers' insistence on the confidentiality of transaction prices like AMP. Setting aside the DOJ's misleading reading of the confidentiality provision in the AMP statute,[12] its theory contradicts its own scienter argument. If, as the DOJ now claims, manufacturers' concerns regarding the confidentiality of AMPs somehow prevented HCFA/CMS from comparing – even internally – AMPs with AWPs, then there is ***no*** basis to contend that Roxane understood that these ***same*** confidential transaction prices should have been openly published as AWPs for the whole world to see. The DOJ cannot have it both ways. In any event, Roxane's unrebutted testimony regarding its understanding of AWP establishes a genuine factual dispute that precludes summary judgment. *See Mylan Labs.*, 608 F. Supp. at 154-55 ("'[I]t is unusual to grant summary judgment on scienter' except in cases where 'the nonmoving party rests merely upon conclusory allegations, improbable inferences, and unsupported speculation.'" (quoting *SEC v. Ficken*, 546 F.3d 45, 51 (1st Cir. 2008))).[13]

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[12] The DOJ misleadingly omits the key statutory phrase that AMP data is "confidential and shall not be disclosed . . . ***in a form which discloses the identity of a specific manufacturer or wholesaler [or], prices charged for drugs by such manufacturer or wholesaler***." 42 U.S.C. § 1396r–8(b)(3)(D) (emphasis added); *see also* (Defs.' Comm. 56.1 ¶¶ 20-29) Thus, the confidentiality provisions only prevented HCFA/CMS from publicly disclosing Roxane's specific AMPs because of competitive harm. Nothing in statute prevented HCFA/CMS from reviewing AMP data internally or sharing it with the States for purposes of comparing it with published AWPs. The DOJ's position is also at odds with HCFA's own interpretation of these provisions in early 1990s, as well as the OIG's understanding of them. (Defs.' Comm. 56.1 ¶¶ 4-8)

[13] The DOJ relies on a selective assortment of documents, which it cites entirely out of context, to purportedly show that Roxane "marketed the spread." Roxane's corporate designee testified, however, that she "wouldn't begin to know how" to market the spread. (US Resp. 56.1 ¶ 110) This alone raises a dispute of material fact.

III. THE DOJ CANNOT ESTABLISH CAUSATION FOR CLAIMS BASED ON THE DMERCS' MISCLASSIFICATIONS OF NOVAPLUS AS A BRAND.

To establish causation, the DOJ must prove that it was reasonably foreseeable that some – but not all – DMERCs would inconsistently classify the Novaplus products as brand drugs, rather than generics. *See, e.g., U.S. ex rel. Franklin v. Parke-Davis*, 2003 WL 22048255, at *4-6 (D. Mass. Aug. 22, 2003).[14] Roxane is entitled to summary judgment because the DOJ fails to come forward with evidence that could support that conclusion. The DOJ ignores the following undisputed facts showing that Roxane *always* considered Novaplus products generics, and provided every indication of this belief to the marketplace:

- The product name, "Ipratropium Bromide Inhalation Solution 0.02% (Novaplus)," contains the full generic chemical compound name, "ipratropium bromide." (Rox. 56.1 ¶¶ 135-42; US Rox. 56.1 Resp. ¶¶ 135-42)
- The Novaplus product entered the marketplace *years* after the patent expired on the brand drug (Atrovent), and amidst a plethora of established generic drugs – *all* of which were identically named as "ipratropium bromide." (Rox. 56.1 ¶¶ 135-42; US Rox. 56.1 Resp. ¶¶ 135-36, 138-41)
- The Novaplus product had identical published AWPs and near-identical contract prices to the Roxane-label product, which no one disputes was a generic drug. (Rox. 56.1 ¶¶ 143-46; US Rox. 56.1 Resp. ¶¶ 143-46)
- The First Databank compendia specifically identified the Novaplus product as a generic drug *on all six* of its generic indicators. (Rox. 56.1 ¶¶ 216-220; US Rox. 56.1 Resp. ¶¶ 217-220)

In spite of this, some DMERCs nonetheless misclassified the Novaplus products as brands. The DOJ seeks to capitalize on these errors to the tune of a ***$1 billion windfall*** in theoretical damages

[14] The DOJ advocates that this Court reverse its prior decision in *Franklin* and adopt a "but-for" causation standard. This Court's prior decision is squarely consistent with law in this circuit and the majority of other circuits, holding that causation under a punitive statute like the FCA requires showing not only "but-for" causation but also proximate cause (under a foreseeability test). *See AWP Litig.*, 478 F. Supp. 2d 164, 175 (D. Mass. 2007); *see also U.S. ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 n.9 (1st Cir. 2007), *overruled on other grounds; see U.S .ex rel. Sikkenga v. Regence Bluecross Blueshield*, 472 F.3d 702, 714-15, n.17 (10th Cir. 2006); *U S. ex rel. Cantekin v. Univ. of Pittsburgh*, 192 F.3d 402, 416 (3rd. Cir. 1999); *U.S. v. Miller*, 645 F.2d 473, 476 (5th Cir. 1981); *Fago*, 518 F. Supp. 2d at 122 (explaining that D.C. Circuit requires proximate cause); *U.S. ex rel. Kinney v. Hennepin County Med. Ctr.*, 2001 WL 964011, *9-10 (D. Minn. Aug. 22, 2001); *see also* John T. Boese, *Civil False Claims and Qui Tam Actions*, § 2.05; *but see U.S. v. First Nat'l Bank of Cicero*, 957 F.2d 1362, 1374 (7th Cir. 1992); *U.S. v. Eghbal*, 475 F. Supp. 2d 1008, 1014-15 (C.D. Cal. 2007). The DOJ's far-reaching proposal to convert the FCA into a strict liability statute flies in the face of well-established case law, and should be rejected.

– even though these misclassifications had *no* impact on Medicare payments in the real world. (Rox. 56.1 ¶¶ 242-45; Rox. Br. 13-14) The DOJ concedes that these products were rarely – if ever – reimbursed under Medicare Part B. (Rox. 56.1 ¶¶ 151-55) There is no basis in law or fact for such an inequitable result.

The DOJ's argument fails because it has no evidence to show that Roxane could have reasonably foreseen the DMERCs' unpredictable classifications of drugs. *See Russo v. Baxter Healthcare Corp.*, 140 F.3d 6, 11 (1st Cir. 1998); *U.S. ex rel. Fago v. M&T Mortg. Corp.*, 518 F. Supp. 2d 108, 122 (D.D.C. 2007) (granting defendant summary judgment where FCA plaintiff could not prove proximate causation). *First*, the DOJ's entire argument depends on a strained and inaccurate interpretation of a HCFA definition of brand drugs, the plain reading of which leads to the opposite result. *Second*, the undisputed evidence demonstrates that not even the DMERCs were able to consistently or predictably implement this HCFA definition with respect to Novaplus products. Thus, the DOJ's conclusory assertion that the DMERCs' misclassifications of the Novaplus products as brands were foreseeable is flatly contradicted by the evidence. At most, the evidence shows significant ambiguity and confusion about the applicability of this definition to the Novaplus drugs, and it is well settled that there is no FCA liability where the defendant cannot reasonably be charged with understanding the import of regulations. *See, e.g., Medica-Rents Co.*, 285 F. Supp. 2d at 770-71 (affirming summary judgment where DMERCs disagreed on which Medicare billing code applied).

A. The DOJ's Strained And Illogical Interpretation Of HFCA's Definition Of Brand Drugs Is Wrong As A Matter of Law.

The DOJ's entire argument depends on a strained and formalistic reading of a HCFA definition of brand drugs, which contravenes the well-established principle that regulatory provisions should be read to avoid absurd results. *See, e.g., Kelly v. U.S.*, 826 F.2d 1049, 1052-53 (Fed Cir. 1987).

Specifically, the DOJ relies on the following HCFA definition of a brand drug:

> Our definition of a "brand" is any product that is marketed under a name other than the generic chemical name of the drug. If a manufacturer chooses to market its product under a proprietary name ***rather than the generic chemical name of the drug***, we believe this is a brand.

(Rox. 56.1 ¶ 174-75; US Rox. 56.1 Resp. ¶ 174) The HCFA definition of brand focuses on the absence of the "generic chemical name of the drug." Here, there is no dispute that the Novaplus products had the full generic chemical name of the drug, "ipratropium bromide," in the marketed name: "Ipratropium Bromide Inhalation Solution 0.02% (Novaplus)." The word "Novaplus" identified the labeler name,[15] and was appended after the generic chemical compound name of the drug. Thus, the word "Novaplus" was not used *rather than* the generic chemical name of "ipratropium bromide," but was used *in addition to* it. Under a plain reading of the definition, the Novaplus drug was a generic, not a brand.

The DOJ's erroneous interpretation focuses *exclusively* on the labeler-identifying word "Novaplus," which constructively erases the entire generic chemical compound name from the product's name. This makes no interpretive sense as the definition focuses not on the labeler name, but on the generic chemical name. Indeed, the hard copy versions of the Redbook compendia (which the DMERCs relied on) listed the Novaplus NDCs without including the term "Novaplus." (Rox. 56.1 ¶¶ 189, 202) As shown below, the 2001 Annual Redbook listed the Novaplus NDCs (0054-8404-11, 13, 21) *identically* to the Roxane-label NDCs (0054-8402-11, 13, 21):

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[15] "Novaplus" is a label used by Novation GPO on over 300 generic products sold exclusively to Novation's GPO members. Novation does not make its own generic drugs. Instead, it contracts with manufacturers to make these drugs and then markets them under a Novaplus private label. Here, Novation contracted to put a Novaplus label on Roxane's generic ipratropium bromide. (Rox. Br. 13, n. 11; Rox. 56.1 ¶ 141)

(Roxane)
SOL, IH (S.D.V.,5X5,PROTECTAPAK)
0.02%,
2.500 ml 25s UD . . . **00054-8402-11** 44.06 **AN**
(S.D.V.,6X5,PROTECTAPAK)
0.02%,
2.500 ml 30s UD . . . **00054-8402-13** 52.87 **AN**
(S.D.V.,12X5,PROTECTAPAK)
0.02%,
2.500 ml 60s UD . . . **00054-8402-21** 105.74 **AN**
SOL, IH (S.D.V.,5X5, PROTECTAPAK)
0.02%,
2.500 ml 25s UD . . . **00054-8404-11** 44.06 **AN**
(S.D.V.,6X5 PROTECTAPAK)
0.02%,
2.500 ml 30s UD . . . **00054-8404-13** 52.87 **AN**
(S.D.V.,12X5,PROTECTAPAK)
0.02%,
2.500 ml 60s UD . . . **00054-8404-21** 105.74 **AN**

As can be seen, the term "Novaplus," the DOJ's sole defense for classifying this drug as a brand, is nowhere to be found in this listing. Moreover, the description of the products and the reported AWPs are identical for the respective package sizes for the Roxane and Novaplus-label NDCs.

Faced with Redbook listings that directly contravene its newfound gloss on HCFA's definition, the DOJ instead attempts to re-write the evidentiary record with new declarations from two of the four DMERCs, where they now claim they did not review the hard copy versions of the Redbook excerpted above, but rather reviewed *only* the electronic CD-ROM versions of Redbook.[16] As with the DOJ's fanciful interpretation of the HCFA definition, these declarations are plainly litigation-driven results.[17] In any event, they are of no avail because they only attenuate causation further by introducing yet another unforeseeable intervening factor – the specific *format* of the Redbook. Incredibly, the DOJ's $1 billion theoretical windfall depends exclusively on whether a particular DMERC independently decided to consult only the electronic version of Redbook, as opposed to the hard copy version. There is, of course, no evidence that Roxane could foresee this.

Setting aside this fundamental causation problem, even the listings in the electronic version of Redbook illustrate the nonsensical nature of the DOJ's interpretation, and the inability of Roxane to

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16 Because the DOJ never produced these CDs during discovery and provided Roxane with only a handful of print-outs from these databases, Roxane has moved this Court for spoliation sanctions. (*See* Dkt. No. 6254, Rox. Defs.' Mot. for Finding of Spoliation at 4-5)

17 The DOJ's position prior to adding the Novaplus drugs to the complaint was that these drugs had "***always*** been considered generics." (Rox. Br. 23) In fact, it is well documented that the OIG also considered Novaplus ipratropium bromide to be a branded product. (Rox. 56.1 ¶¶ 307-18)

foresee these odd classification results. Below is an excerpt of how the Novaplus NDCs were listed in the Redbook electronic CD-ROM, which is the DOJ's basis to justify Novaplus being a "brand":

Red Book(TM) for Windows®

Product Information

Product	Manuf/Dist	Identifier	Form	Strength	Size	UD	AWP
IPRATROPIUM BROMIDE	Allscripts	54569-4910-00	SOL	0.02%	2.500 ml 25s	U	18.62
IPRATROPIUM BROMIDE	Alpharma USPD	00472-0751-23	SOL	0.02%	2.500 ml 25s	U	56.50
IPRATROPIUM BROMIDE	Apotex Corp.	60505-0806-01	SOL	0.02%	2.500 ml 25s		56.00
ATROVENT	Boehr Ingelheim Phar	00597-0080-62	SOL	0.02%	2.500 ml 25s	U	70.97
IPRATROPIUM BROMIDE	Dey	49502-0685-03	SOL	0.02%	2.500 ml 25s	U	44.10
IPRATROPIUM BROMIDE	Dey	49502-685030	SOL	0.02%	2.500 ml 25s	U	44.10
IPRATROPIUM BROMIDE	Ivax Pharm	00172-6407-44	SOL	0.02%	2.500 ml 25s	U	44.10
IPRATROPIUM BROMIDE	Phys Total Care	54868-4082-01	SOL	0.02%	2.500 ml 25s	U	23.54
IPRATROPIUM BROMIDE	Roxane	00054-8402-11	SOL	0.02%	2.500 ml 25s	U	44.06
IPRATROPIUM BROMIDE-NOVAPLUS	Roxane	00054-8404-11	SOL	0.02%	2.500 ml 25s	U	44.06
IPRATROPIUM BROMIDE	Alpharma USPD	00472-0751-30	SOL	0.02%	2.500 ml 30s	U	67.80
IPRATROPIUM BROMIDE	Dey	49502-0685-33	SOL	0.02%	2.500 ml 30s	U	52.80
IPRATROPIUM BROMIDE	Dey	49502-685330	SOL	0.02%	2.500 ml 30s	U	52.80
IPRATROPIUM BROMIDE	Roxane	00054-8402-13	SOL	0.02%	2.500 ml 30s	U	52.87
IPRATROPIUM BROMIDE-NOVAPLUS	Roxane	00054-8404-13	SOL	0.02%	2.500 ml 30s	U	52.87
IPRATROPIUM BROMIDE	Alpharma USPD	00472-0751-60	SOL	0.02%	2.500 ml 60s	U	118.80
IPRATROPIUM BROMIDE	Dey	49502-685600	SOL	0.02%	2.500 ml 60s	U	105.60
IPRATROPIUM BROMIDE	Dey	49502-0685-60	SOL	0.02%	2.500 ml 60s	U	105.60
IPRATROPIUM BROMIDE	Ivax Pharm	00172-6407-49	SOL	0.02%	2.500 ml 60s	U	105.60
IPRATROPIUM BROMIDE	Phys Total Care	54868-4082-00	SOL	0.02%	2.500 ml 60s	U	42.25
IPRATROPIUM BROMIDE	Roxane	00054-8402-21	SOL	0.02%	2.500 ml 60s	U	105.74
IPRATROPIUM BROMIDE-NOVAPLUS	Roxane	00054-8404-21	SOL	0.02%	2.500 ml 60s	U	105.74

But even a cursory glance at this listing shows that, like *every other* generic ipratropium bromide product in this list, the Novaplus-label NDCs contain the name of the generic chemical compound, "IPRATROPIUM BROMIDE," front-and-center. The additional "NOVAPLUS" word, which is separated by a dash and added only *after* the chemical compound name, serves to distinguish the Novaplus products from the Roxane products. In contrast, the true brand product here was named "ATROVENT," which, consistent with the HCFA definition of brand, had "a proprietary name rather than the generic chemical name of the drug." Thus, the DOJ's own evidence establishes the sensible interpretation of the HCFA definition: a drug named "Atrovent" is properly classified as a brand because it is marketed under a proprietary name *rather than* the generic chemical name of "ipratropium bromide." The same would hold for such proprietary drug names as "Tylenol" and "Advil," which are proprietary marketing names rather than the generic chemical names of "acetaminophen" and "ibuprofen." This comports with standard naming conventions in the pharmaceutical industry (and common sense). The DOJ's contrary view requires that *any* additional term to a generic chemical name, even one that merely identifies the labeler, converts the product

into a brand. Thus, "Walgreens' ibuprofen" and "Rite Aid's acetaminophen" become "brand" drugs. This is an absurd interpretation, and one the Court must reject as a matter of law. *See Kelly*, 826 F.2d at 1052-53. In any event, the DOJ does not have a shred of evidence to show that Roxane could have reasonably foreseen such nonsensical results. Indeed, as shown directly below, not even the DMERCs applied the DOJ's litigation-driven interpretation in any consistent fashion.

B. The DMERCs Did Not Consistently Or Predictably Apply The DOJ's Litigation-Driven Interpretation Of The HCFA Definition.

The DOJ's conclusory assertions that (1) the HCFA definitional comment was "clear" with respect to Novaplus drugs, and (2) all four DMERCs implemented this purportedly "clear rule" are fictions flatly contradicted by the actual record evidence, which shows the absence of any consistent methodology. (Rox. Br. 16-22) For instance, the following are undisputed facts:

- The Adminastar DMERC representative unambiguously testified that she classified the Novaplus products based on whether the products were capitalized in the printed Redbook – a methodology that had *nothing* to do with the HCFA definition the Government now embraces. (Rox. 56.1 ¶ 180)
- The Cigna DMERC representative testified that she classified drugs as brands based on whether a cross-reference employing the word "see" was listed in the printed Redbook – again, a methodology divorced from the HCFA directive. (*Id.* ¶ 181)
- DMERC-A, unlike the other DMERCs, (correctly) classified the Novaplus ipratropium bromide as a *generic* throughout the entire time period. (*Id.* ¶ 221)
- The Adminastar DMERC misclassified the *Roxane-label* ipratropium bromide – a product that no one in this litigation disputes should have been classified as a generic – as brand for more than a year. (*Id.* ¶ 223)

Having ***no*** response to these undisputed facts, the DOJ simply ignores them and again relies on new declarations it solicited from two DMERCs, who now claim that, unlike their counterparts in Adminastar and DMERC-A, they classified Novaplus drugs as brands based on their determination that the name "Ipratropium Bromide - NovaPlus" was a "label name other than the generic chemical name." (Henderson Common Ex. 3 (Decl. of C. Helton), ¶ 28-29; Fauci Ex. 163 (Decl. of R. Stone), ¶ 7-8) Even assuming these untested declarations to be true, they are a nullity because the evidentiary record demonstrates that *even these two DMERCs* failed to consistently implement their

newly declared "rules," and did not in fact uniformly classify Novaplus drugs as brands. (Rox. 56.1 ¶¶ 298-306) Specifically, the DOJ selectively attaches to the declarations a handful of pricing arrays showing that the Cigna and Palmetto DMERCs *sometimes* classified Novaplus drugs as brands – but it omits other pricing arrays that demonstrate that these *same* DMERCs simultaneously (and inconsistently) also classified other Novaplus drugs as generics. For instance, Cigna classified "Doxorubicin Novaplus" as a generic in 2001 and 2002 even though the Redbook CD printouts listed Doxorubicin *identically* to the way they listed Novaplus ipratropium bromide. Cigna also classified "Bumetanide Novaplus" as a generic in 2001. Similarly, Palmetto listed "Diltiazem HCl Novaplus" and "Cytarabine Novaplus" as generics in 2002 and 2003, respectively. (*Id.* ¶¶ 299-304)

Thus, not even the DOJ's manufactured "best" evidence shows that the HCFA definition provided any sort of "clear rule," much less one that predictably led to Novaplus drugs being classified as generics. Simply put, if the DMERCs entrusted with correctly interpreting and implementing HCFA's definition were incapable of doing so in a consistent and predictable fashion, then there can be no basis to conclude that Roxane could foresee these unpredictable applications.[18] Even in the light most favorable to the DOJ, the evidence may show, at most, ambiguity as to whether a product that contains *both* the generic chemical name and a labeler name should be classified as a brand under HCFA's definition. But it is well-settled that regulatory ambiguity cannot be the basis of FCA liability, much less sufficient to establish causation for the astronomical alleged damages that the DOJ seeks here based on the DMERCs' errors. *Cf. U.S. ex rel. Lamers v. City of*

[18] Indeed, the DOJ fails to establish that Roxane was on constructive notice of HCFA's definition, which was never codified in any final rule or regulation but appeared only in response to a public comment in the Federal Register. The DOJ's cited authority applies only to promulgated *regulations* and *affected parties*. Neither condition is met here. This comment was directed at Medicare carriers and Roxane is not a signatory to any contractual benefit in the Medicare program. Moreover, it is undisputed that Novaplus was *rarely if ever* reimbursed under Medicare Part B. (Rox. 56.1 ¶¶ 151-55) Thus, there is no basis to place Roxane on constructive notice. *Cf. Nw. Tissue Ctr. v. Shalala*, 1 F.3d 522, 536 (7th Cir. 1993).

Green Bay, 168 F.3d 1013, 1018 (7th Cir. 1999) ("[D]ifferences in interpretation growing out of a disputed legal question are . . . not false under the FCA."); *Medica-Rents Co.*, 285 F. Supp. 2d at 770.

IV. THE DOJ HAS NO EVIDENCE TO ESTABLISH SCIENTER WITH RESPECT TO THE NOVAPLUS PRODUCTS.

The DOJ's two-sentence response on scienter ignores the controlling law on evidentiary requirements for establishing scienter, as well as the unrebutted evidence demonstrating that Roxane always considered Novaplus products generics and named and priced them accordingly. (U.S. Rox. Br. 26) Instead, the DOJ merely repeats its argument with respect to causation, an entirely different element under the FCA, which fails for the reasons noted above. Here, the DOJ does not point to a shred of evidence to establish that Roxane even knew about, let alone intentionally or recklessly disregarded, HCFA's definition of "brand drug." *See, e.g.*, *K&R Ltd.*, 530 F.3d at 983; *Madonna Towers, Inc.*, 278 F.3d at 768. Further, the DOJ cannot show that Roxane's view that Novaplus ipratropium bromide was a generic product, under a definition stating that a brand drug is a drug marketed under a proprietary name *rather than* a chemical compound name, was "objectively unreasonable." *See Safeco*, 551 U.S. at 69-70 & n.20; *K&R Ltd.*, 530 F.3d at 983. To the contrary, the undisputed facts demonstrate that the Novaplus ipratropium product entered a marketplace already saturated with generic drugs, all of which were named "ipratropium bromide." (Rox. 56.1 ¶¶ 135-42) Roxane also reported identical AWPs and had identical contract prices for both the Novaplus and Roxane drugs. Marketplace indicators confirmed its generic status. (*Id.* ¶¶ 143-46) For instance, *all six generic indicators* in the FDB Blue Book identified Novaplus as a generic, and HCFA guidance specifically noted the FDB Blue Book as a source of pricing for the DMERCs. (*Id.* ¶¶ 163, 216-20)

Nor does the Government have any evidence to show that Roxane even contemplated that its Novaplus drugs might be reimbursed under Medicare. *First*, it is undisputed that there were virtually *no* Medicare Part B claims paid for Novaplus ipratropium bromide because these products were sold

primarily to hospitals, and therefore likely paid under Medicare Part A (which does not pay for drugs separately). (Rox. 56.1 ¶¶ 151-55) *Second*, Roxane could not even know of the errors because the DMERCs' classifications of brands or generics were not publicly available. (*Id.* ¶ 162) Accordingly, there is no evidentiary basis to establish that Roxane's reporting of AWPs had *anything* to do with the DMERCs' subsequent misclassifications of these drugs, much less that Roxane intentionally or recklessly disregarded any regulations or definitions with respect to Medicare.

V. THE DOJ CANNOT ESTABLISH CAUSATION OR SCIENTER FOR CLAIMS BASED ON THE DMERCS' FAILURES TO UPDATE PRICING ARRAYS.

The DMERCs' failures to properly include Zenith Goldline products in their pricing arrays is yet another example of their failure to adhere consistently to regulatory mandates – and another instance where the DOJ seeks to capitalize on DMERC mistakes to gain a windfall that is unrelated to any conduct by Roxane. Three DMERCs undisputedly failed to include AWPs in their pricing arrays for Zenith Goldine products, which were available in the Redbook beginning in April 2000. (*Id.* ¶¶ 163, 185, 198, 245-46, 251) Although alleged damages sought from Roxane properly cease for one DMERC as of April 2000 (because of its timely incorporation of Zenith Goldline AWPs), the DOJ nonetheless continues to compute purported damages of approximately $88 million based on a disregard of the other DMERCs' undisputed failure to similarly update prices. (*Id.* ¶¶ 249-50, 252)

The DOJ's response concedes (as it must) that HCFA regulations required the DMERCs to include ***all sources*** of the generic form of a drug in their pricing arrays. (*Id.* ¶¶ 16, 159; US Rox. 56.1 Resp. ¶¶ 52, 174; *see also* 42 C.F.R. § 405.517(c)). It attempts to wish away this regulatory mandate through the Palmetto DMERC's new declaration, which suggests that Palmetto had a "policy" of excluding preservative-free products (such as Zenith Goldline) from its pricing arrays. (Fauci Ex. 163 ¶ 17) The DOJ also notes certain other DMERC representatives' testimony that they did not always include all generic forms of a drug in their arrays. (Rox. 56.1 ¶ 169; US Rox. 56.1 Resp. ¶¶ 169, 245, 247, 251-52; Fauci Ex. 163 ¶ 16)

This proves Roxane's point. The undisputed fact that three of the four DMERCs regularly did something other than follow HCFA's directive to include *all* sources of generic AWPs is the paradigmatic example of an intervening cause that cuts off damages. *See Russo*, 140 F.3d at 11; *Fago*, 578 F. Supp. 2d at 122. Nor could the DMERCs' internal discretionary choices to exclude certain prices have been foreseeable to Roxane, and the DOJ does not bother to provide any evidence that shows otherwise. Instead, the DOJ dismissively asserts that "the DMERCs were under no legal obligation to update their arrays within any specific time frame" or to update arrays "perfectly." These protestations of "timeliness" or "perfection" are misleading distractions: the undisputed fact is that these DMERCs ***never*** included the Zenith Goldline product over a period of ***years,*** while their counterpart did. This falls well short for establishing causation for treble damages under the FCA.

VI. THE DOJ IS NOT ENTITLED TO SUMMARY JUDGMENT ON MEDICARE CLAIMS PROCESSED BY THE CIGNA DMERC.

With no explanation, the DOJ seeks summary judgment on materiality and causation for a limited number of claims processed by the Cigna DMERC. It fails to reveal to this Court, that for over one year of the relevant period, Cigna depended on the pricing arrays prepared by the Adminastar DMERC. (Rox. 56.1 Resp. ¶ 155) Such piecemeal attempts at summary judgment in light of this evidentiary record are inappropriate. *First*, as explained above, the Government cannot prevail as a matter of law on *any* of the core elements under the FCA, including materiality and causation. *Second*, it cannot establish causation for damages due to Cigna's failure to include the Zenith Goldline NDCs beginning in April 2000. *Third*, as explained below, all claims after December 31, 2000 are barred.

VII. THE DOJ HAS NO EVIDENCE THAT ROXANE'S AWPS OR WACS WERE ACTUALLY "THE BASIS ON WHICH CLAIMS WERE MADE."

To establish falsity, the DOJ must show that (1) each AWP was objectively false, and (2) that the false AWP was the "basis on which the claim was *made*." (US Rox. Br. 13) Here, the DOJ has no evidence that any *claim*, at the time it was presented for payment by a provider to any of the 49

different State Medicaid programs, actually incorporated Roxane's AWPs or WACs (by virtue of the State's estimated acquisition cost ("EAC") calculation or otherwise). At the threshold, Roxane's connection to the claim actually submitted for payment is even more legally tenuous than claims at issue in the typical State AWP cases. Here, the DOJ contends that the Forms 37 and 64 submitted to CMS – *not* the actual provider claims submitted to the various Medicaid programs – were somehow false, but offers no evidence to support its argument, nor any evidence to connect Roxane's AWPs and WACs to those forms. (Defs.' Comm. 56.1 Resp. ¶¶ 85-91) Thus, because the DOJ has failed to show any "false" Form 37 or Form 64 – indeed, it never produced in discovery or attached to its summary judgment papers any actual State-submitted Form 37 or Form 64 that it contends was false – the DOJ's motion on all Medicaid claims must be denied and summary judgment in Roxane's favor is warranted.

In any event, with respect to the actual provider submissions, the DOJ cannot simply assume that all of the millions of Medicaid claims here, which span over a ten-year period, utilized Roxane's allegedly false AWPs and WACs based solely on the State Medicaid payment formulae and the *ad hoc* testimony from Medicaid officials who claim that compendia prices were generally used. An FCA case requires sufficient evidence to establish that each Medicaid claim at issue, when presented, was in fact false.[19] Thus, the DOJ must set forth evidence that Roxane's AWPs or WACs were *in fact* part of the Medicaid claims themselves and that the individual Medicaid programs believed those AWPs and WACs represented fully discounted, empirical averages of selling prices.[20] There is no such evidence, and thus the DOJ's Medicaid counts fail. *See Mylan Labs.*, 608 F. Supp. 2d at 139-40.

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19 *U.S. ex rel. Garst v. Lockheed-Martin Corp.*, 2002 WL 1794004, *2–3 (N.D. Ill. Aug. 2, 2002) (relator must "connect allegedly false statements to specific claims for payment").

20 State Medicaid programs, not the federal government, set Medicaid payment rates. (Defs.' Comm. Br. 4-6; Rox. 56.1 Reply ¶ 275)

VIII. THE DOJ CANNOT ESTABLISH LIABILITY OR DAMAGES ON CLAIMS WHERE IT LACKS EVIDENCE OF THE BASIS OF PAYMENT.

The DOJ cannot establish liability under the FCA by extrapolation because there is *no* evidence of how any particular claim was actually paid.[21] This argument is not a "conflation" of liability with damages. (US Rox. Br. 22) Rather, it is the law of this Court: there must be a "causal link between the [defendant's] actions" and the actual payment. *See In re AWP Litig.*, 478 F. Supp. 2d at 180 (dismissing portion of California's Medicaid claims because State did not establish link between alleged wrongdoing and the State's MAC payments, which "ceased to be based on prices [allegedly] falsely reported by defendants"); *Mylan Labs.*, 608 F. Supp. 2d at 147-48 (granting defendants' summary judgment motion where reimbursement did not adhere to CMS-approved State Medicaid plan, or payment regulations). The DOJ ignores these basic requirements.

Roxane is entitled to summary judgment on (1) all Medicaid claims relating to 33 Medicaid programs because the DOJ improperly relies on extrapolation to establish liability and (2) the claims of 16 Medicaid programs where claims data was not used. (Rox. Br. 4-9) The DOJ can never establish liability on these claims because it admits "the datasets contained in the SMRF/MAX/MSIS data do not contain the data required to calculate the basis of payment for a claim" and the SDUD data is *aggregated* data, which likewise can never reveal the basis of payment on any claim. (US Rox. 56.1 Resp. ¶ 267-68) Roxane is also entitled to summary judgment on any claim *not* paid on the basis of a published EAC formula that used AWPs or WACs (Rox. Br. 9-12), or any drug claim involving a drug subject to a FUL.[22] The DOJ admits:

- The DOJ has offered no evidence on the basis of payment on any claim. The DOJ's expert did not set out to determine the basis of payment for any Medicaid claims. (U.S. Rox. 56.1

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[21] Nor is there undisputed evidence of materiality on any Medicaid claim, which precludes the entry of summary judgment in the DOJ's favor. (Defs.' Comm. Br. 32-36)

[22] Federal law regarding FUL drugs does not incorporate EAC. *See* 42 C.F.R. § 447.332. Thus, the DOJ's argument on "regulatory constraints" of EAC has no bearing on FUL drugs. (US Comm. Br. 10-11)

Resp. ¶ 275) Nor did he examine "whether CMS approved the reimbursement formulas utilized by the various state Medicaid programs." (*Id.* ¶ 269)

- Medicaid claims should be discarded where the paid amount exceeds the amount that should have been paid under the regulations, or is inconsistent with the State Medicaid reimbursement policy. (*Id.* ¶ 284)
- State Medicaid programs have deviated from the CMS-approved methodology. (*Id.* ¶¶ 270-72, 274 ("The [DOJ] does not dispute that Alabama Medicaid used AWP to determine its EAC when a WAC price was not available, or that the approved State Plan did not specify the use of AWP when a WAC price was not available."); Rox. 56.1 Reply ¶ 277 (Rhode Island's use of AWP-15% was not part of a CMS-approved Medicaid plan)); *Mylan Labs.*, 608 F. Supp. 2d at 147-48.
- The DOJ's expert did not determine whether FUL prices applied to the Medicaid claims at issue, although several of Roxane's drugs were subject to FUL prices. Moreover, many State Medicaid programs do not base their MAC prices on published prices, and no State Medicaid program bases its U&C on AWPs or WACs. (U.S. Rox. 56.1 Resp. ¶¶ 120, 276, 278-79)

In sum, the causal link between Roxane's alleged conduct and the payment of a particular Medicaid claim is not met by mechanically comparing re-imagined AWPs to the paid amount.

IX. THE DOJ HAS NO RESPONSE TO THE 2001 "PERFECT STORM OF INFORMATION" THAT NEGATES SCIENTER AND FALSITY.

This Court's finding in the MDL that "[b]y 2001, there was a perfect storm of information that reflected the size of the spreads, largely because of the compelling information collected by the HHS Office of Inspector General ('OIG')," *In re AWP Litig.*, 491 F. Supp. 2d at 41, coupled with widespread evidence in this case that the Government had long known about the so-called "mega-spreads" between AWP and acquisition costs for generic drugs and in particular for Roxane's drugs such as ipratropium bromide, (Rox. 56.1 ¶¶ 1-95), preclude a finding of FCA liability post-2000.[23] (Rox. Br. 25-34) The DOJ has no response to the "perfect storm of information." Nor could it: "The government knew. The government knew. The government knew. At least from all those OIG reports, they knew." *In re AWP Litig.*, CA No. 01-12257-PBS, Mot. Hr'g, 11/5/07 at 46.

[23] The DOJ's contention that "Roxane does not dispute the falsity of its prices prior to December 31, 2000" is disingenuous and just plain wrong. (US Rox. Br. 13) To be clear, Roxane does indeed dispute that its AWPs were ever false, but moved for partial summary judgment only on claims post-2000 under this argument based on this Court's prior holding that there was "perfect storm" of pricing information by that time.

The DOJ refuses to engage this Court's "perfect storm" holding, as well as its holding in *Mylan Labs.* that government knowledge was a viable defense when compendia benchmarks were used as a policy matter. *Mylan Labs.*, 608 F. Supp. 2d at 150, 152. The DOJ instead contorts the government knowledge case law to avoid the overwhelming evidence of government acquiescence to payments for generic drugs that substantially exceeded acquisition costs. (Defs.' Comm. Br. 2-20) The DOJ is wrong on the law. Both falsity and scienter can be vitiated by evidence of government approval or acquiescence. The law, as articulated by this Court in *Mylan Labs.*, does not require particularized statements of approval directed at the individual defendants, nor does it require an "official pronouncement by [a] government agency directing them to report false prices" or that Roxane relied upon any official government communication. (US Comm. Br. 32-35; US Rox. Br. 18); *Mylan*, 608 F. Supp. 2d at 150, 152. As noted above, ***even today***, the Government continues to utilize AWP as a basis for Medicaid and Medicare Part D reimbursement payments, fully encouraging generic drug mega-spreads of 270% because it "provides good value to both the beneficiary and the taxpayer." (Rox. 56.1 ¶ 79) Thus, the DOJ's suggestion that the voluminous evidence in this record can never serve to negate the elements of a FCA claim is legally wrong, especially with respect to the post-2000 time period.[24] (*See* Appendix A)

X. THE DOJ CANNOT ESTABLISH UNJUST ENRICHMENT.

The DOJ's response mentions several *potential* theories for recovery, but circumvents the undisputed fact that it has ***no*** competent evidence to establish its unjust enrichment claim. "Liability

[24] Whether the OIG stated that it believed reimbursement payments were excessive is beside the point. Such statements do not alter the conclusion that the Government continued to pay reimbursement based on AWP, even in the face of the widespread awareness that it was paying amounts significantly greater than actual acquisition costs. In fact, even if the OIG viewed reimbursement payments as too high, it was also well aware that its myopic focus on drug costs overlooked other key components of drug reimbursement policy, such as access to care, political impediments, and historically inadequate dispensing fees. Indeed, HCFA/CMS itself took issue with the notion that AWP-based reimbursement resulted in "overpayment," as "the regulations and relevant state plans authorize payment for drugs based on AWPs, *regardless of whether those prices are inflated*." (Defs.' Comm. 56.1¶ 72) (emphasis added)

in unjust enrichment involves a showing that wealth is 'in one person's hands when it should be in another's.'" *Mass v. Mylan Labs.*, 357 F. Supp. 2d 314, 324 (D. Mass 2005). Further, the DOJ must prove there was a "causal nexus" connecting Roxane's enrichment with the Government's lost "wealth." *See Holmes Prods. Corp. v. Dana Lighting, Inc.*, 958 F. Supp. 27, 36 (D. Mass. 1997). But the DOJ fails to explain what "wealth" is in Roxane's hands "when it should be in another's," as well as the causal nexus between Roxane's alleged wrongful conduct and the Government's detriment. Because Roxane receives no reimbursement payments from government payors and the Government is not a competitor who lost sales to Roxane, the DOJ cannot explain, let alone prove, how Roxane has been unjustly enriched at the Government's expense. *See Dialogo, LLC v. Bauza*, 456 F. Supp. 2d 219, 228 (D. Mass. 2006); Restatement (First) of Restitution, § 1 cmt. c.

Even if the DOJ had evidence to establish some form of an unjust enrichment claim, it has ***no*** evidence to quantify the alleged harm.[25] None of its experts have conducted any analyses of market share changes, changes in profits, or competitive spreads related to alleged AWP manipulation. The DOJ cannot proceed on a claim that requires the jury to speculate about Roxane's alleged – but entirely unsubstantiated – enrichment. *See County Line Inv. Co. v. Tinney*, 933 F.2d 1508, 1518 (10th Cir. 1991). The DOJ's unjust enrichment claim thus fails.

CONCLUSION

For all the foregoing reasons and the reasons stated in the Roxane's opening brief and in Defendants' Common Brief, the Court should grant the Roxane Defendants' motion for summary Judgment and deny the Government's motion for summary judgment.

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[25] The DOJ's claim that it has "ample evidence" that Roxane sales increased as spreads increased consists of only *one* instance when Roxane raised *one* product's AWP. (US Rox. Br. 33) Even if the DOJ's proffered facts were true – which they are not (Rox. 56.1 Resp. ¶¶ 74-88) – they fail to show how Roxane's increased sales were the Government's sales, nor can the DOJ prove that pharmacies were paid *more* because of an increased AWP on furosemide, which was subject to a FUL at all relevant times. (Rox. 56.1 ¶ 120)

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on August 28, 2009, a copy to LexisNexis File and Serve for posting and notification to all parties.

/s/ John W. Reale
John W. Reale

Appendix A

Representative Studies And Surveys of Drug Acquisition Costs

Studies and Surveys of Pharmacy Acquisition Costs

Year of Report	State	Source	Acquisition Cost Average Discount from AWP
1996	California	OIG - US Dept. of Health and Human Services	41.4%
1996	Montana	OIG - US Dept. of Health and Human Services	48.5%
1996	Florida	OIG - US Dept. of Health and Human Services	41.5%
1996	North Carolina	OIG - US Dept. of Health and Human Services	45.2%
1996	Delaware	OIG - US Dept. of Health and Human Services	37.0%
1996	Virginia	OIG - US Dept. of Health and Human Services	45.1%
1996	New Jersey	OIG - US Dept. of Health and Human Services	39.9%
1996	Nebraska	OIG - US Dept. of Health and Human Services	44.9%
1997	Missouri	OIG - US Dept. of Health and Human Services	46.4%
1997	District of Columbia	OIG - US Dept. of Health and Human Services	43.8%
1997	Maryland	OIG - US Dept. of Health and Human Services	41.9%
1997	Eleven-State National Sample	OIG - US Dept. of Health and Human Services	42.5%
1999	Utah	OIG - US Dept. of Health and Human Services (in assoc. with the Utah Dept. of Health)	60.1%
1999	Kentucky	Myers & Stauffer LC	60.0% (Drugs with FUL) 32.3% (Drugs without FUL)
1999	Louisiana	Myers & Stauffer LC	69.6% (Drugs with FUL) 32.6% (Drugs without FUL)
2000	Kentucky	Myers & Stauffer LC	77.5% (Drugs with FUL) 30.2% (Drugs without FUL)
2001	Arkansas	Myers & Stauffer LC	82.5% (Drugs with FUL) 32.3% (Drugs without FUL)
2001	Kentucky	Myers & Stauffer LC	83.4% (Drugs with FUL) 34.9% (Drugs without FUL)
2001	Washington	OIG - US Dept. of Health and Human Services	65.3%
2001	Colorado	OIG - US Dept. of Health and Human Services	65.2%
2001	Texas	OIG - US Dept. of Health and Human Services	62.8%
2001	Indiana	OIG - US Dept. of Health and Human Services	66.7%
2001	West Virginia	OIG - US Dept. of Health and Human Services	68.9%
2002	Montana	OIG - US Dept. of Health and Human Services	65.4%
2002	Florida	OIG - US Dept. of Health and Human Services	68.2%
2002	Wisconsin	OIG - US Dept. of Health and Human Services	67.3%
2002	California	Myers & Stauffer LC	85.9% (Drugs with FUL) 34.8% (Drugs without FUL)

Source: Rox. 56.1 Reply ¶¶ 21, 47, 64.